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Data Evaluation Record on the Acute Toxicity of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....} **EPA MRID Number 47567517**

Data Requirement:

PMRA Data Code:	9.8.4 (TGAI) or 9.8.6 (EP)
EPA DP Barcode:	360307
OECD Data Point:	IIA 8.12 (TGAI) and IIIA 10.8.1.1 (EP)
EPA Guideline:	850.4150

Test material: **0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L (AIs: Fluopyram and Trifloxystrobin, respectively)**

Purity: 21.4% w/w Fluopyram and 21.6% w/w Trifloxystrobin

Common name Fluopyram
Chemical name: IUPAC: N-{2-[3-Chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}-α,α,α-trifluoro-o-toluamide
CAS name: N-[2-[3-Chloro-5-(trifluoromethyl)-2-pyridinyl]ethyl]-2-(trifluoromethyl)benzamide
CAS No.: 658066-35-4
Synonyms AE C656948

Common name Trifloxystrobin
Chemical name: IUPAC: Methyl (*E*)-methoxyimino-{(*E*)-α-[1-(α,α,α-trifluoro-*m*-tolyl)ethylideneaminooxy]-*o*-tolyl}acetate
CAS name: Methyl (α*E*)-α-(methoxyimino)-2-[[[[(1*E*)-1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]benzeneacetate
CAS No.: 141517-21-7
Synonyms CGA 279202

Primary Reviewer: Moncie Wright
Staff Scientist, Cambridge Environmental

Signature: Moncie V Wright
Date: 10/23/09

Secondary Reviewer: Teri S. Myers
Senior Scientist, Cambridge Environmental

Signature: Teri S Myers
Date: 11/19/09

Primary Reviewer: F. Nicholas Mastrota
Wildlife Biologist
Environmental Fate and Effects Division
Environmental Protection Agency

Date: 03/23/11 F. Nicholas Mastrota

EPA PC Code: 129112 and 080302

Date Evaluation Completed: 23-03-2011

CITATION: Gosch, H., and D.H. Nguyen. 2007. Non-target terrestrial plants: an evaluation of the effects of AE C656948 + Trifloxystrobin SC 250 + 250 g/L in the vegetative vigour test (Tier 1). Unpublished study performed and sponsored by Bayer CropScience AG, Ecotoxicology, Frankfurt am Main, Germany. Study Identification No. VV07/03. Study completed June 28, 2007.

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Data Evaluation Record on the Acute Toxicity of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....} **EPA MRID Number 47567517**

EXECUTIVE SUMMARY:

The effect of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L (AIs: Fluopyram and Trifloxystrobin, respectively) on the vegetative vigor of monocot (corn, *Zea mays*; oat, *Avena sativa*; and onion, *Allium cepa*) and dicot (cucumber, *Cucumis sativa*; oilseed rape, *Brassica napus*; sugarbeet, *Beta vulgaris*; soybean, *Glycine max*; sunflower, *Helianthus annuus L*; buckwheat, *Fagopyrum esculentum*; and tomato, *Lycopersicon esculentum*) crops was studied at nominal concentrations of 0 (negative control), and 0.75 L product/ha (equivalent to 0.782 lbs product/A). The concentrations of the active ingredients were 0 (negative control), and 0.167 lbs fluopyram/A, and 0 (negative control), and 0.169 lbs trifloxystrobin/A.

The growth medium used in the vegetative vigor test was a sandy-silt loam soil (pH 7.31, % organic carbon 1.3%). After 21 days, the numbers of plants survived were recorded and taken for measuring dry weight.

Survival was 100% in the control and treated conditions for all species tested.

There was promotion of growth in dry weight for soybean, buckwheat, corn, and onion (ranging from -5 to -118%, respectively). Sunflower and oat had inhibitions of 0.3 and 7.9%, respectively. Cucumber, oilseed rape, sugarbeet, and tomato had inhibitions ranging from 12.6 to 31.3%.

There was no phytotoxicity in this study.

The most sensitive monocot species could not be determined due to the lack of an effect on any of the monocots tested. Therefore, the overall NOAEC and EC_{25} values for monocot species was 0.782 and >0.782 lbs prod/A, respectively, which is equivalent to 0.167 and >0.167 lbs Fluopyram/A, respectively and 0.169 and >0.169 lbs Trifloxystrobin/A, respectively. The most sensitive dicot species were cucumber, oilseed rape, sugarbeet, and tomato based on dry weight, with NOAEC and EC_{25} values of <0.782 lbs prod/A, which is equivalent to <0.167 lbs Fluopyram/A, and <0.169 lbs Trifloxystrobin/A.

Sugarbeet had an inhibition of 31.3%, which triggers the necessity for Tier II testing for this species. OCSPP guidelines suggest Tier II testing if the inhibition for any species in a Tier I test is equal to or exceeds 25%.

Maximum Labeled Rate: Not reported

Results Synopsis

0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L

Monocot

EC_{50}/IC_{50}: >0.782 lbs prod/A 95% C.I.: N/A
EC_{25}/IC_{25}: >0.782 lbs prod/A 95% C.I.: N/A
EC_{05}/IC_{05}: <0.782 lbs prod/A 95% C.I.: N/A
NOAEC: 0.782 lbs prod/A
Slope: N/A Std err: N/A
Most sensitive monocot: Could not be determined
Most sensitive parameter: Could not be determined

Dicot

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Data Evaluation Record on the Acute Toxicity of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L to Terrestrial Vascular Plants: Vegetative Vigor

EC_{50}/IC_{50}: >0.782 lbs prod/A 95% C.I.: N/A
EC_{25}/IC_{25}: <0.782 lbs prod/A 95% C.I.: N/A
EC_{05}/IC_{05}: <0.782 lbs prod/A 95% C.I.: N/A
NOAEC: <0.782 lbs prod/A
Slope: N/A Std err: N/A
Most sensitive dicot: Cucumber, oilseed rape, sugar beet, and tomato
Most sensitive parameter: Dry weight

AI: Fluopyram

Monocot

EC_{50}/IC_{50}: >0.167 lbs Fluopyram/A 95% C.I.: N/A
EC_{25}/IC_{25}: >0.167 lbs Fluopyram/A 95% C.I.: N/A
EC_{05}/IC_{05}: <0.167 lbs Fluopyram/A 95% C.I.: N/A
NOAEC: 0.167 lbs Fluopyram/A
Slope: N/A Std err: N/A
Most sensitive monocot: Could not be determined
Most sensitive parameter: Could not be determined

Dicot

EC_{50}/IC_{50}: >0.167 lbs Fluopyram/A 95% C.I.: N/A
EC_{25}/IC_{25}: <0.167 lbs Fluopyram/A 95% C.I.: N/A
EC_{05}/IC_{05}: <0.167 lbs Fluopyram/A 95% C.I.: N/A
NOAEC: <0.167 lbs Fluopyram/A
Slope: N/A Std err: N/A
Most sensitive dicot: Cucumber, oilseed rape, sugar beet, and tomato
Most sensitive parameter: Dry weight

AI: Trifloxystrobin

Monocot

EC_{50}/IC_{50}: >0.169 lbs Trifloxystrobin/A 95% C.I.: N/A
EC_{25}/IC_{25}: >0.169 lbs Trifloxystrobin/A 95% C.I.: N/A
EC_{05}/IC_{05}: >0.169 lbs Trifloxystrobin/A 95% C.I.: N/A
NOAEC: 0.169 lbs Trifloxystrobin/A
Slope: N/A Std err: N/A
Most sensitive monocot: Could not be determined
Most sensitive parameter: Could not be determined

Dicot

EC_{50}/IC_{50}: >0.169 lbs Trifloxystrobin/A 95% C.I.: N/A
EC_{25}/IC_{25}: <0.169 lbs Trifloxystrobin/A 95% C.I.: N/A
EC_{05}/IC_{05}: <0.169 lbs Trifloxystrobin/A 95% C.I.: N/A
NOAEC: <0.169 lbs Trifloxystrobin/A
Slope: N/A Std err: N/A
Most sensitive dicot: Cucumber, oilseed rape, sugar beet, and tomato
Most sensitive parameter: Dry weight

This toxicity study is classified as supplementary. It does not satisfy the guideline requirement for a Tier I Terrestrial Plant Vegetative Vigor toxicity study.

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Data Evaluation Record on the Acute Toxicity of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....} **EPA MRID Number 47567517**

Table 1 (Tier I studies). Summary of effects for all species at the 0.782 lbs prod/A treatment level.

	Survival (%)			Dry weight (g)		
Species	**Control**	**Treatment**	**%difference**	**Control**	**Treatment**	**%difference**
Corn	100	100	0	4.945	5.475	-10.7
Oat	100	100	0	1.434	1.320	7.9
Onion	100	100	0	0.045	0.097	-117.5
Cucumber	100	100	0	4.551	3.627	20.3
Oilseed rape	100	100	0	3.870	3.383	12.6
Soybean	100	100	0	2.953	3.089	-4.6
Sugarbeet	100	100	0	2.389	1.641	31.3
Sunflower	100	100	0	3.790	3.780	0.3
Tomato	100	100	0	1.663	1.289	22.5
Buckwheat	100	100	0	2.673	3.498	-30.9

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: This study was conducted according to OECD Guideline for Testing of Chemicals, Guideline 227, Terrestrial (Non-target) Plant Test: Vegetative Vigour Test (July 2006), which is reported as being equivalent to U.S. EPA OCSPP Guideline No. 850.4150. The following deviations from OCSPP 850.4150 were noted:

1. Shoot height was not a measured parameter in this study. This growth parameter is required in the OCSPP 850.4150 guidance and would have been particularly useful to examine in this study, given that there were significant effects on the other required growth parameter (i.e., dry weight).
2. The study author did not provide adequate watering information.
3. The study author did not provide raw data for survival, but there was no mortality in this study.
4. Only three monocot species were tested; OCSPP guidelines suggest that four monocots be tested.
5. The test did not include a dicot root crop as required by EPA.
6. The percent humidity was not reported.
7. This study did not meet requirements for EPA FIFRA Good Laboratory Practices. Also, a Quality Assurance Statements were not provided.
8. The method and depth of planting was not reported.

These deviations impacted the acceptability of the study.

COMPLIANCE: A signed and dated No Data Confidentiality statement was provided. GLP and Quality Assurance statements were not provided. This study was not conducted in compliance with U.S. EPA FIFRA GLP standards (40 CFR Part 160). The registrant reported that the report was not subject to GLP.

A. MATERIALS:

1. Test Material **0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L (AIs: Fluopyram and Trifloxystrobin, respectively)**

Description: White suspension

Lot No./Batch No. : 2007-000441 (Batch no.)

Purity: 21.4% w/w Fluopyram and 21.6% w/w Trifloxystrobin

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Stability of compound under test conditions: Analytical verification was not performed.
(OECD recommends chemical stability in water and light)

Storage conditions of test chemicals: The test material was stored at room temperature.

Table 2. Physical/chemical properties of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L.

Parameter	Values	Comments
Water solubility at 20EC	Not reported	
Vapor pressure	Not reported	
UV absorption	Not reported	
pKa	Not reported	
Kow	Not reported	

2. Test organism:

Monocotyledonous species: Corn (*Zea mays*; Poaceae; Magister), Oat (*Avena sativa*; Poaceae; Flamings Stern), and Onion (*Allium cepa*; Liliaceae; Braunschweiger blutrote); *EPA recommends four monocots in two families, including corn.*

Dicotyledonous species: Cucumber (*Cucumis sativus*; Cucurbitaceae; Delikatess), Oilseed rape (*Brassica napus*; Brassicaceae; Licapo), Soybean (*Glycine max*; Fabaceae; Erin), Sugarbeet (*Beta vulgaris*; Chenopodiaceae; Mosaik), Sunflower (*Helianthus annuus L.*; Asteraceae; Solara), Tomato (*Lycopersicon esculentum*; Solanaceae; Balkonstar), and Buckwheat (*Fagopyrum esculentum*; Polygonaceae; variety not reported); *EPA recommends six dicots in four families, including soybean and a root crop.*

OECD recommends a minimum of three species selected for testing, at least one from each of the following categories: Category 1: ryegrass, rice, oat, wheat, and sorghum; Category 2: mustard, rape, radish, turnip, and Chinese cabbage; Category 3: vetch, mung bean, red clover, fenugreek, lettuce, and cress.

Seed source: Commercial seed sources via Bayer CropScience AG, Horticulture, H 872, 65926 Frankfurt am Main, Germany.
Prior seed treatment/sterilization: Seeds were not treated with pesticides or repellents prior to test initiation.
Historical % germination of seed: Not reported
Seed storage, if any: Seeds were refrigerated.

B. STUDY DESIGN:

1. Experimental Conditions

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a. Limit test: A limit test was not described.

b. Range-finding study: A range-finding study was not conducted.

c. Definitive Study

Table 3: Experimental Parameters - Vegetative Vigor

Parameters	Vegetative Vigor	
	Details	**Remarks** *Criteria*
Duration of the test	21 days	*Recommended test duration is 14-21 days.*
Number of seeds/plants replicate	4 plants per replicate pot for all species except oat and onion 5 plants per replicate pot for oat and onion	*Five plants per replicate are recommended.*
Number of plants retained after thinning	Not reported	
Number of replicates Control: Adjuvant control: Treated:	4 for oat and onion; 5 for all others N/A 4 for oat and onion; 5 for all others	*Four replicates per dose are recommended*
Test concentrations (nominal) Formulation in L/ha: Formulation in lbs ai/A: Fluopyram in lbs ai/A: Trifloxystrobin in lbs ai/A: Measured:	0 (negative control), and 0.75 L product/ha 0 (negative control), and 0.782 lbs product/A 0 (negative control), and 0.167 lbs fluopyram/A 0 (negative control), and 0.169 lbs trifloxystrobin/A N/A	*Five test concentrations should be used with a dose range of 2X or 3X progression*
Method and interval of	N/A – analytical verification not	

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Data Evaluation Record on the Acute Toxicity of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L to Terrestrial Vascular Plants: Vegetative Vigor

PMRA Submission Number {.....} **EPA MRID Number 47567517**

Parameters	Vegetative Vigor	
	Details	Remarks *Criteria*
analytical verification LOQ: LOD:	performed	
Adjuvant (type, percentage, if used)	N/A	
Test container (pot) Size/Volume Material: (glass/polystyrene)	10 and 13 cm diameter Plastic	*Non-porous containers should be used.* *OECD recommends that non-porous plastic or glazed pots be used.*
Growth facility	Glasshouse	
Method/depth of seeding	Not reported	
Test material application Application time including the plant growth stage Number of application Application interval Method of application	Test material was applied at time 0. Each species was treated once N/A; single application Test material was sprayed onto the plant foliage using a spray chamber equipped with an overhead nozzle set at 35 cm above the sprayed surface.	Plants used in the test were in the 2-4 leaf growth stage.
Details of soil used Geographic location Depth of soil collection Soil texture	Not reported Not reported Sandy-silt loam that was sterilized, fertilized, and sieved to 2 mm	Lime content: 1.2%

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PMRA Submission Number {.....} **EPA MRID Number 47567517**

Parameters	Vegetative Vigor	
	Details	**Remarks**
		Criteria
% sand % silt % clay pH: % organic carbon CEC Moisture at 1/3 atm (%)	16.7 59.1 24.2 7.31 1.3% Not reported Not reported	*EPA prefers soil mixes containing sandy loam, loam, or clay loam soil with no greater than 2% organic matter. Glass beads, rock wool, and 100% acid washed sand are not preferred..* *OECD prefers the soil to be sieved (0.5 cm) to remove coarse fragments. Carbon content should not exceed 1.5% (3% organic matter). Fine particles (under 20um) makeup should be between 10 and 20%. The recommended pH is between 5.0 and 7.5.*
Details of nutrient medium, if used	N/A	
<u>Watering regime and schedules</u> Water source/type: Volume applied: Interval of application: Method of application:	 Not reported Not reported. Reported as being applied as needed for plant growth. Plants were bottom watered.	Soil moisture was checked daily. *EPA prefers that under foliage watering or bottom watering be utilized for vegetative vigor studies so that the chemical is not washed out of the soil during the test.*
Any pest control method/fertilization, if used	N/A	
<u>Test conditions</u> Temperature: Photoperiod: Light intensity and quality: Relative humidity:	 Day: 23 ± 8°C; Night: 18 ± 8°C 16L:8D Natural daylight was supplemented by artificial lighting >15000 lux lamps turn off, >50000 lux shading closes Not reported	 *EPA prefers that the cold vs warm loving plants be tested in two separate groups to optimize plant growth.* *OECD prefers that the temperature, humidity and light conditions be suitable for maintaining normal growth of each species for the test period.*
<u>Reference chemical (if used)</u> Name: Concentrations:	 N/A	

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PMRA Submission Number {.....} **EPA MRID Number 47567517**

Parameters	Vegetative Vigor	
	Details	Remarks *Criteria*
Other parameters, if any	None	

2. Observations:

Table 4: Observation Parameters - Vegetative Vigor

Parameters	Vegetative Vigor	
	Details	Remarks
Parameters measured (i.e., plant height, dry weight or other endpoints)	Survival, phytotoxicity, growth stages, and dry weight.	Shoot height was not measured in this study. Growth stages assessed according to BBCH-Monograph – Growth Stages.
Measurement technique for each parameter	Survival, growth stages, and phytotoxicity were assessed visually. Dry weight determination methods were not reported.	
Observation intervals	Phytotoxicity was assessed at days 7, 14, and 21. Survival, growth stages, and dry weight were determined at test termination.	
Other observations, if any	None.	
Were raw data included?	Raw data were only included for dry weight.	
Phytotoxicity rating system, if used	0- No injury or effect; A- slight symptoms throughout the whole plant or more moderate symptoms on a small area; B- moderate symptoms throughout the whole plant or severe symptoms on a limited area; C- severe symptoms throughout the whole plant with younger or newly developed leaves growing	Assessed using EPPO Standard 135.

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Parameters	Vegetative Vigor	
	Details	**Remarks**
	normally; D- total plant symptoms with the plant showing poor vigor; and E-moribund	

II. RESULTS and DISCUSSION:

A. INHIBITORY EFFECTS:

Vegetative Vigor:

Survival was 100% in the controls and across all species tested.

There was promotion of growth in dry weight for soybean, buckwheat, corn, and onion (ranging from -5 to -118%, respectively). Sunflower and oat had inhibitions of 0.3 and 7.9%, respectively. Cucumber, oilseed rape, sugarbeet, and tomato had inhibitions ranging from 12.6 to 31.3%.

There was no phytotoxicity in this study. All species were in the same growth stages as compared to the control groups.

The study authors reported that there was no adverse effect on the survival and phytotoxicity of all ten species tested. Inhibitions observed for cucumber, oilseed rape, sugarbeet, and tomato were statistically significant, but none reached or exceeded the 50% trigger for further testing. Toxicity values were not reported.

B. REPORTED STATISTICS:

Dry weight data were statistically analyzed using a Pairwise Mann-Whitney-U-test at the 95% level of confidence (one-sided smaller). Survival was not analyzed due to a lack of inhibition for all species tested.

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Table 5: Reported effect of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L on Vegetative Vigor.

Species	Results summary for survival (lbs product/A)							
	%	NOAEC	EC_{05}	95%CI	EC_{25}	95%CI	EC_{50}	95%CI
Corn	100	NR	NR	NR	NR	NR	NR	NR
Oat	100	NR	NR	NR	NR	NR	NR	NR
Onion	100	NR	NR	NR	NR	NR	NR	NR
Cucumber	100	NR	NR	NR	NR	NR	NR	NR
Oilseed rape	100	NR	NR	NR	NR	NR	NR	NR
Soybean	100	NR	NR	NR	NR	NR	NR	NR
Sugarbeet	100	NR	NR	NR	NR	NR	NR	NR
Sunflower	100	NR	NR	NR	NR	NR	NR	NR
Tomato	100	NR	NR	NR	NR	NR	NR	NR
Buckwheat	100	NR	NR	NR	NR	NR	NR	NR

NR- not reported

Table 5a: Reported effect of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L on Vegetative Vigor.

Species	Results summary for dry weight (lbs product/A)							
	Weight (g)	NOAEC	EC_{05}	95%CI	EC_{25}	95%CI	EC_{50}	95%CI
Corn	4.945-5.475	NR	NR	NR	NR	NR	NR	NR
Oat	1.320-1.434	NR	NR	NR	NR	NR	NR	NR
Onion	0.045-0.097	NR	NR	NR	NR	NR	NR	NR
Cucumber	3.627-4.551	NR	NR	NR	NR	NR	NR	NR
Oilseed rape	3.383-3.870	NR	NR	NR	NR	NR	NR	NR
Soybean	2.953-3.089	NR	NR	NR	NR	NR	NR	NR
Sugarbeet	1.641-2.389	NR	NR	NR	NR	NR	NR	NR
Sunflower	3.780-3.790	NR	NR	NR	NR	NR	NR	NR
Tomato	1.289-1.663	NR	NR	NR	NR	NR	NR	NR
Buckwheat	2.673-3.498	NR	NR	NR	NR	NR	NR	NR

NR- not reported

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Plant Injury Index										
Control	Corn	Oat	Onion	Cucumber	Oilseed rape	Soybean	Sugarbeet	Sunflower	Tomato	Buckwheat
0	0	0	0	0	0	0	0	0	0	0

0- No injury or effect; A- slight symptoms throughout the whole plant or more moderate symptoms on a small area; B- moderate symptoms throughout the whole plant or severe symptoms on a limited area; C- severe symptoms throughout the whole plant with younger or newly developed leaves growing normally; D- total plant symptoms with the plant showing poor vigor; and E- moribund

C. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:

Any species exhibiting an inhibition of 5% or greater for dry weight relative to the negative control was statistically analyzed; toxicity values for all other species and endpoints were determined visually. All analyses were conducted using the negative control. The treatment group was compared to the negative control using a two-tailed t-test in Excel 2003. All analyses were conducted using the nominal application rate in terms of lbs product/A. Survival was not statistically analyzed due to 100% survival of all species; toxicity values were visually determined.

Table 6: Effect of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L on Vegetative Vigor.

Species	Results summary for survival (lbs product/A)									
	%	NOAEC	EC_{05}	95%CI	EC_{25}	95%CI	EC_{50}	95%CI	slope	Std err
Corn	100	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Oat	100	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Onion	100	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Cucumber	100	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Oilseed rape	100	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Soybean	100	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Sugarbeet	100	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Sunflower	100	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Tomato	100	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Buckwheat	100	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A

N/A - not applicable

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Data Evaluation Record on the Acute Toxicity of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L to Terrestrial Vascular Plants: Vegetative Vigor

Table 6a: Effect of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L on Vegetative Vigor.

Species	Results summary for dry weight (lbs product/A)									
	Weight (g)	NOAEC	EC_{05}	95%CI	EC_{25}	95%CI	EC_{50}	95%CI	slope	Std err
Corn	4.945-5.475	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Oat	1.320-1.434	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Onion	0.045-0.097	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Cucumber	3.627-4.551	<0.782	<0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Oilseed rape	3.383-3.870	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Soybean	2.953-3.089	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Sugarbeet	1.641-2.389	<0.782	<0.782	N/A	<0.782	N/A	>0.782	N/A	N/A	N/A
Sunflower	3.780-3.790	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Tomato	1.289-1.663	<0.782	<0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A
Buckwheat	2.673-3.498	0.782	>0.782	N/A	>0.782	N/A	>0.782	N/A	N/A	N/A

N/A - not applicable

Plant Injury Index										
Control	Corn	Oat	Onion	Cucumber	Oilseed rape	Soybean	Sugarbeet	Sunflower	Tomato	Buckwheat
0	0	0	0	0	0	0	0	0	0	0

0- No injury or effect; A- slight symptoms throughout the whole plant or more moderate symptoms on a small area; B- moderate symptoms throughout the whole plant or severe symptoms on a limited area; C- severe symptoms throughout the whole plant with younger or newly developed leaves growing normally; D- total plant symptoms with the plant showing poor vigor; and E- moribund

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Monocot

EC_{50}/IC_{50}: >0.782 lbs prod/A 95% C.I.: N/A
EC_{25}/IC_{25}: >0.782 lbs prod/A 95% C.I.: N/A
EC_{05}/IC_{05}: <0.782 lbs prod/A 95% C.I.: N/A
NOAEC: 0.782 lbs prod/A
Slope: N/A Std err: N/A
Most sensitive monocot: Could not be determined
Most sensitive parameter: Could not be determined

Dicot

EC_{50}/IC_{50}: >0.782 lbs prod/A 95% C.I.: N/A
EC_{25}/IC_{25}: <0.782 lbs prod/A 95% C.I.: N/A
EC_{05}/IC_{05}: <0.782 lbs prod/A 95% C.I.: N/A
NOAEC: <0.782 lbs prod/A
Slope: N/A Std err: N/A
Most sensitive dicot: Sugarbeet
Most sensitive parameter: Dry weight

D. STUDY DEFICIENCIES:

Shoot height was not measured in this study. This endpoint is a required parameter in the OCSPP 850.4150 guidance and data on its performance would have been particularly interesting in this study, given the significant reductions ($p<0.05$) observed for dry weight of several species, including the most sensitive dicot (sugarbeet).

E. REVIEWER=S COMMENTS:

The study author did not report ECx and NOAEC values. Therefore, the reviewer's results are presented in the Executive Summary, Conclusion, and Summary Tables sections of this DER.

The product tested in this study contained two active ingredients: fluopyram and trifloxystrobin. The reviewer has presented results in terms of the product and the two active ingredients in the Executive Summary and Conclusions sections of this DER.

The study author's and the reviewer's results were similar in terms of detecting statistically significant reductions for cucumber, sugarbeet, and tomato dry weight, relative to the control weights. However, the study author additionally detected a significant reduction ($p<0.05$) for oilseed rape dry weight, while the reviewer's analysis did not. This is probably due to the difference in statistical methods used and the fact that the study author used a one-tailed test. The study author used a Pairwise Mann-Whitney-U-test, while the reviewer used a two-tailed t-test to compare the control and treated groups. The p-value for the reviewer's results for the two-tailed test was 0.08, and for a one-tailed test would have been $p = 0.04$. Inhibition in the treated group was 13% for oilseed rape dry weight.

Sugarbeet dry weight was inhibited 31.3%, suggesting that this species should be tested further in a Tier II study.

The study author did not provide raw data for survival. In this case it was not an issue due to lack of inhibition for any species.

Only three monocot species were tested; OCSPP guidelines suggest that four monocots be tested.

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The geographic location and depth of soil collection of the soil used for the definitive test was not reported.

The CEC and moisture content of the soil was not reported.

The method and depth of planting was not reported.

The percent humidity was not reported.

The study author reported dry weight per plant, but did not specifically state the units; they were assumed to be in grams.

The study author did not provided adequate watering information.

All species were tested under similar environmental conditions.

The experimental work was conducted from April 12 to May 14, 2007.

F. CONCLUSIONS:

Because of the significant deviations from the OCSPP test guidelines, this study is classified as supplementary. The most sensitive monocot species could not be determined due to the lack of an effect on any of the monocots tested. Therefore, NOAEC and EC_{25} values for monocot species was 0.782 and >0.782 lbs prod/A, respectively, which is equivalent to 0.167 and >0.167 lbs Fluopyram/A, respectively and 0.169 and >0.169 lbs Trifloxystrobin/A, respectively. The most sensitive dicot species were the cucumber, oilseed rape, sugarbeet, and tomato, based on dry weight, with NOAEC and EC_{25} values of <0.782 lbs prod/A, which is equivalent to <0.167 lbs Fluopyram/A and <0.169 lbs Trifloxystrobin/A.

Most sensitive monocot and EC_{25}: None, >0.782 lbs prod/A
Most sensitive dicot and EC_{25}: Cucumber, oilseed rape, sugarbeet, and tomato (dry weight); <0.782 lbs prod/A; <0.167 lbs Fluopyram/A; <0.169 lbs Trifloxystrobin/A

III. REFERENCES:

1 BBA (Mai 2000): EPPO Standard PP 1/135 (2), Phytotoxicity Assessment.
2 BBCH – Monograph. Growth stages of Mono- and Dicotyledonous Plants. Federal Biological Research Centre for Agriculture and Forestry, 1997.
3 Chemikaliengesetz der Bundesrepublik Deutschland (ChemG), Anhang 1, in der Fassung der Bekanntmachung vom 20.06.2002 (BGBl. I S.2090).
4 DIN 18123 (April 1983) Baugrunduntersuchung von Bodenproben. Bestimmung der Korngrobenverteilung.
5 DIN 19682-2 (Marz 1973) Bodenuntersuchungsverfahren im landwirtschaftlichen Wasserbau, Felduntersuchungen. Ermittlung der Bodeneart.
6 OECD (July 2006): Guideline for the testing of chemicals, Guideline 227, "Terrestrial (Non-Target) Plant Test: Vegetative Vigour Test."
7 The OECD Principles of Good Laboratory Practice, adopted by Council on 26th November 1997 [C(97)186/Final], Environment Directorate, Organization for Economic Cooperation and Development, Paris 1998.
8 Ratte, M. ToxRat Professional (version 2.09, release 27.01.2005). ToxRat Solutions GmbH, Naheweg 15, 52477 Alsdorf.

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Data Evaluation Record on the Acute Toxicity of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L to Terrestrial Vascular Plants: Vegetative Vigor

APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

Cucumber dry weight	*Control*	*0.782 lbs prod/A*
Mean	4.551	3.6268
Variance	0.078556	0.2053087
Observations	5	5
Pooled Variance	0.14193235	
Hypothesized Mean Difference	0	
df	8	
t Stat	3.878781109	
P(T<=t) one-tail	0.002341423	
t Critical one-tail	1.859548033	
P(T<=t) two-tail	0.004682845	
t Critical two-tail	2.306004133	

Oilseed rape dry weight	*Control*	*0.782 lbs prod/A*
Mean	3.87	3.3828
Variance	0.1873745	0.0998897
Observations	5	5
Pooled Variance	0.1436321	
Hypothesized Mean Difference	0	
df	8	
t Stat	2.032598164	
P(T<=t) one-tail	0.038274025	
t Critical one-tail	1.859548033	
P(T<=t) two-tail	0.076548051	
t Critical two-tail	2.306004133	

Sugarbeet dry weight	*Neg control*	*0.782 lbs prod/A*
Mean	2.389	1.641
Variance	0.2274055	0.0576835
Observations	5	5
Pooled Variance	0.1425445	
Hypothesized Mean Difference	0	
df	8	
t Stat	3.132538157	
P(T<=t) one-tail	0.006980827	
t Critical one-tail	1.859548033	
P(T<=t) two-tail	0.013961653	
t Critical two-tail	2.306004133	

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Data Evaluation Record on the Acute Toxicity of 0.75 L/ha AE C656948 + Trifloxystrobin SC 250 + 250 g/L to Terrestrial Vascular Plants: Vegetative Vigor

Tomato dry weight	*Control*	*0.782 lbs prod/A*
Mean	1.6624	1.289
Variance	0.0893693	0.0384325
Observations	5	5
Pooled Variance	0.0639009	
Hypothesized Mean Difference	0	
df	8	
t Stat	2.335558934	
P(T<=t) one-tail	0.023872777	
t Critical one-tail	1.859548033	
P(T<=t) two-tail	0.047745554	
t Critical two-tail	2.306004133	

Oat dry weight	*Neg control*	*0.782 lbs prod/A*
Mean	1.4335	1.31975
Variance	0.016491667	0.004358917
Observations	4	4
Pooled Variance	0.010425292	
Hypothesized Mean Difference	0	
df	6	
t Stat	1.575514107	
P(T<=t) one-tail	0.083103649	
t Critical one-tail	1.943180274	
P(T<=t) two-tail	0.166207298	
t Critical two-tail	2.446911846	

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